



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 5, 2016

Susan Stracquatano
Delta Analytical Corporation
Agent for Angelini Pharma Inc.
12510 Prosperity Drive, Suite 160
Silver Spring, MD 20904

Subject: PRIA Label Amendment to Add Additional Microorganisms
Product Name: BLEACH-WIPE
EPA Registration Number: 65787-2
Application Date: March 16, 2016
Decision Number: 515196

Dear Ms. Stracquatano:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Ben Chambliss by phone at (703) 308-8174, or via email at chambliss.ben@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "DF", with a long horizontal stroke extending to the right.

Demson Fuller, Product Manager 32
Regulatory Management Branch II
Antimicrobials Division (7510P)
Office of Pesticide Programs

Enclosure

[LOGO]

[CAT # [09041][09053]]

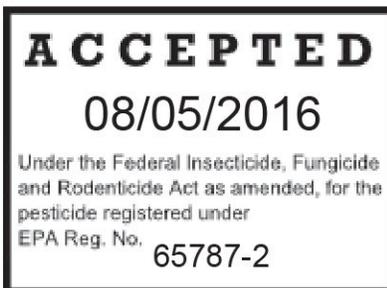
TM

BLEACH-WIPE

[Alternate Brand Name: **Alcavis Bleach-Wipe**]

FOR INSTITUTIONAL AND COMMERCIAL USE ONLY

Bleach Disinfectant Wipe



For [disinfecting] [wiping] hard non-porous environmental surfaces and patient care equipment

Active ingredient:

Sodium hypochlorite: 0.525%

Other ingredients:..... 99.475%

Total: 100.000%

5,000 ppm Available Chlorine

KEEP OUT OF REACH OF CHILDREN CAUTION

[See [back] [reverse] [box] [label] [side] for [additional] [precautionary statements] [directions for use]]

FIRST AID	
If in eyes:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15 - 20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. In an emergency, call a doctor or Poison Control Center at 1-800-222-1222.	

Manufactured by:
Angelini Pharma Inc.
8322 Helgerman Ct.
Gaithersburg, MD 20877
800-726-2308

EPA Reg. No. 65787-2
EPA Est. No. 65787-MD-001

PREMOISTENED [8" x 10"] [5" x 8"] TOWELETTE
Net Contents: [0.7] [0.4] oz.
[# of TOWELETTES]

Note: Bracketed text [] is optional or an alternate version of text. Italicized Bracketed text [] indicates a reader's note. The terms "wipe(s)" and "towelette(s)", may be used interchangeably throughout label text. F: Shared/Angelini/65787-2/Labels/2016/Bleach Wipe Amend 031616

PRECAUTIONARY STATEMENTS Hazards to Humans and Domestic Animals

CAUTION: Liquid may cause moderate eye irritation. Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.

[Organisms and contact time may be listed, in a table, or other format and in any order.]

[Choose one or more of the following organisms for inclusion on the label.]

[Effective in the presence of a 5% organic soil load against:]

C. difficile Spores [(5 Minute Contact)]

Clostridium difficile spores [ATCC 43598]

Bacteria [(1 Minute Contact)]

Staphylococcus aureus [ATCC 6538]

Pseudomonas aeruginosa [ATCC 15442]

Salmonella enterica [ATCC 10708]

TB [(1 Minute Contact)]

Mycobacterium bovis - BCG (TB)

Bacteria [(10 minute Contact)]

[*Staphylococcus aureus* Methicillin Resistant [MRSA][ATCC 33592]]

[*Enterococcus faecalis* Vancomycin Resistant [VRE][ATCC 51299]]

[*Streptococcus pneumoniae* [ATCC 6303]]

[*Streptococcus pyogenes*, [ATCC 12344]]

DIRECTIONS FOR USE:

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling.

Suggested areas of usage:

Medical, Dental and Laboratory Counters, Exam Tables, Carts, Patient Care Equipment, Point of Care Equipment, Telephones, Sink Tops, Toilet Seats

[General Disinfection] [Disinfection] [Directions]:

- Always use personal protective equipment (gloves).
- Open wipe packet.
- Remove premoistened towelette.
- Apply towelette to hard non-porous surface to be disinfected.
- Thoroughly wet surface making sure treated surface remains visibly wet for specified contact time.
- Use additional wipe if needed to assure continuous wet contact time.
- Allow surface area to air dry and discard used towelette.
- Do not re-use used towelette.
- [Preclean prior to disinfecting hard, non-porous surfaces for *C. diff* spores [*Clostridium difficile* spores]. [See [below] [box label] [for] special instructions for cleaning and disinfecting against *C. diff* spores [*Clostridium difficile* spores].

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Special Instructions for Cleaning Prior to Disinfection against *Clostridium difficile* spores:

- Personal Protection: Wear appropriate barrier protection such as gloves, gowns, masks or eye covering.
- Cleaning Procedure: Pre-clean hard, nonporous surfaces. Fecal matter/waste must be thoroughly cleaned from surfaces/objects before disinfection by application with [Bleach-Wipe] [this product]. Cleaning is to include vigorous wiping and/or scrubbing, until all visible soil is removed. Special attention is needed for high-touch surfaces. Surfaces in patient rooms are to be cleaned in an appropriate manner, such as from right to left or left to right, on horizontal surfaces, and top to bottom, on vertical surfaces, to minimize spreading of the spores. Restrooms are to be cleaned last. Do not reuse soiled towelettes.
- Contact time: Treated surface must remain visibly wet for a full [five] [5] minutes. Use additional wipe(s) if needed to ensure surface remains wet for continuous [five] [5] minute contact time.
- Infectious Materials Disposal: Materials used in the cleaning process that may contain feces/wastes are to be disposed of immediately in accordance with local regulations for infectious materials disposal.

[This statement to be used on institutional labels with medical use sites, medical devices, and/or bloodborne pathogens:]

Do not use this product as a terminal sterilant/high level disinfectant on any surface or instrument that is introduced directly into human body, either into or in contact with the bloodstream or normally sterile areas of the body, or contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or otherwise enter normally sterile areas of the body. This product may be used to preclean or decontaminate critical or semi-critical medical devices prior to sterilization or high level disinfection.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Storage: Store this product in a cool, dry area away from direct sunlight and heat.

Towelette Disposal: Do not reuse towelette. Dispose of used towelette and empty pack in trash. Do not flush in toilet.

[batch code] [Lot #]

[Optional claims:]

[Bleach-Wipe is a 1:10 dilution of 5.25% sodium hypochlorite solution with purified water to comply with recommended infection control protocol.]

[Maximum surface area that can be disinfected per towelette is [3' x 3'] [3' x 1.5']]

[Tuberculocidal] [and] [Bactericidal]

[Effective against] [Kills] [*Clostridium difficile*] [*C. difficile*] [*C. diff*] [spores] [ATCC 43598] [in five [5] minutes]

[Premoistened] [Presaturated] [Premeasured] [Disposable]

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F: Shared/Angelini/65787-2/Labels/2016/Bleach Wipe Amend 031616